

## PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 30 JAN 2006

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Applicant's or agent's file reference 15513-1PCT	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/US04/31743	International filing date (day/month/year) 27 September 2004 (27.09.2004)	Priority date (day/month/year) 25 September 2003 (25.09.2003)	
International Patent Classification (IPC) or national classification and IPC IPC(8): A61P 25/00, 25/18, 25/22, 25/24, 15/00, 15/10; A61K 31/496, 31/506, 31/33; C07D 209/00, 209/04 and US CL: 514/183, 415, 427, 254.09, 678; 548/550, 416, 469			
Applicant CENOMED, INC.			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☐ (sent to the applicant and to the International Bureau) a total of \_\_\_ sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒ Box No. I Basis of the report

☐ Box No. II Priority

☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

☐ Box No. IV Lack of unity of invention

☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

☐ Box No. VI Certain documents cited

☐ Box No. VII Certain defects in the international application

☐ Box No. VIII Certain observations on the international application

Date of submission of the demand

10 August 2005 (10.08.2005)

Name and mailing address of the IPEA/US

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Form PCT/IPEA/409 (cover sheet) (April 2005)

Date of completion of this report

22 December 2005 (22.12.2005)

Authorized officer

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# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/31743

## Box No. 1 Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4(a))
  - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☒ the description:
- pages 1-30 as originally filed/furnished
  - pages\* NONE received by this Authority on \_\_\_\_\_
  - pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the claims:
- pages 31-34 as originally filed/furnished
  - pages\* NONE as amended (together with any statement) under Article 19
  - pages\* NONE received by this Authority on \_\_\_\_\_
  - pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the drawings:
- pages NONE as originally filed/furnished
  - pages\* NONE received by this Authority on \_\_\_\_\_
  - pages\* NONE received by this Authority on \_\_\_\_\_

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☒ The amendments have resulted in the cancellation of

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/figs NONE
- ☒ the sequence listing (*specify*): NONE
- ☒ any table(s) related to the sequence listing (*specify*): NONE

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

Form PCT/IPEA/409 (Box No. 1) (April 2005)

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US04/31743

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)

Claims 1-18 YES  
Claims NONE NO

Inventive Step (IS)

Claims 1-18 YES  
Claims NONE NO

Industrial Applicability (IA)

Claims 1-18 YES  
Claims NONE NO

## 2. Citations and Explanations (Rule 70.7)

Claims 1-18 meet the criteria set out in PCT Article 33(2) and (3), because the prior art does not teach or fairly suggest the instant compositions comprising a compound having formula (I).

The prior art reference, FICK et al (WO 03/011396) teach pharmaceutical compositions comprising tetrahydroindolone derivatives linked to arylpiperazines derivatives similar to compound of formula (I) of the instant invention. See page 12, page 16, paragraph [0056] - page 21. FICK also teaches the use of these pharmaceutical compositions for the treatment of psychiatric and neurological diseases. See page 32, paragraph [0108]. However, FICK et al. teaches R6 as H and does not specifically teach R6 (i.e. para substituent) on the arylpiperazine as alkyl, halo, alkoxy, perfluoroalkyl, perfluoroalkoxy, or nitro.

Claims 1-18 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.